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RESEARCH ARTICLE

SAFETY PROGRAM TO ADDRESS ETHICAL ISSUES IN CLINICAL TRIALS

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Abstract

Ethical issues in clinical trials are of worth concern, hence for we propose a safety program that will help in achieving excellence in the conduct of the trials. Our paper presents a clear outline of the safety program under headings as: organizational structure remodeling, site staff training and educational programs, a plan for incident reporting and data collection. The proposed Safety Program has been designed on evidence based practice and is dedicated to achieve patient safety and quality assurance in clinical trials. The proposed program will help institutions to develop guidelines for better research outcomes, improve quality of projects, help in data management, provide training opportunities to site staff, ensure professional excellence and will help stakeholders to collaborate for patient safety.

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Introduction:-

The purpose of the article is to present a clear outline of the safety program that can resolve the issues, risks and gaps in the ethical conduct of clinical trials. It will bring a new approach and strategy for risk based mitigation strategy. The proposed program has been designed on the basis of identified issues in the current practice, summarized findings and proposed solutions and recommendations.

The clear outline of the safety program is as under:

1. Organizational structure remodeling.
2. Site staff training and educational programs.
3. Safety reporting

Organizational structure remodeling:

Organization's hierarchy is the core model that determines the successful execution of a safety program. Team leaders review the errors in the system and design programs to rectify the issues. For the smooth execution of the clinical trials, firm organizational infrastructure with best human resource is the key. (Griffin et al., 2010; Brehaut et al., 2019). Ethical and administrative issues ruin the integrity of clinical trials and also the reputation of the clinical research organization is the field. It blocks the financial growth of the company and its ethical reputation in the clinical research industry. Team leaders bring policies on table and are responsible for further execution of them. Organizational aims can be achieved by a well defined organizational structure (Tucker, 2003). Task allocation and team coordination with leadership supervision make a difference. The structure of the organization affects the actions of the organization. For efficient functioning of the organization, it's important how responsibilities are

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allocated to different entities. The structure provides a platform for the workers to perform and in return worker's skills shape the organization's actions (Griffin et al., 2010; Brehaut et al., 2019). It's a reciprocal equation. The proposed safety program suggests a concrete organizational structure with skilled staff as an essential requisite to address ethical issues and misconduct in clinical trials. Team work with team leaders and open communication amongst site personnel's can resolve ethical misconduct issues in the industry.

Site staff training and educational programs:-

Good Clinical Practice (GCP) Training:

The proposed safety program suggests site staff training as an essential component to avoid ethical issues in the clinical trials. Good Clinical Practice (GCP) ensures ethical conduct of the trial to the scientific standards. It protects the rights of human subject during participation in the clinical trial. Active implementation of GCP principles is essential to avoid ethical misconduct in the trial. It helps in achieving clinical research competence (Largent., 2013). The training should clearly define the significance of investigator's role, FDA 1572, investigator brochure agreement. It should include guidelines separately for device and drug trial. Record retention agreement policies should be clearly explained to the site staff. The training course content should be customized based on the job function. Inform consent process with its current ethical guidelines and process to seek it should be covered as a separate module. IRB guidelines and protocol adherence should be discussed under regulatory compliance. Training should include refresher courses covering new areas and current updates. New training methods and techniques should be used to make the classrooms more interactive. This includes applied training and course presentations, case studies, hypothetical cases, discussion boards, workshops interactive web based modules. The training should be clearly documented for records. Common errors made should be discussed to avoid mistakes. Today is the era of global clinical trials, hence integrated approach to GCP training is mandatory for patient safety. There is non uniformity in the current training program, hence it's essential to streamline GCP training to goals and expectations of research community. The content should include ICH E6, international ethical guidelines for research, ethical review committee administrative role (Sugarman., 2014). The staff should be trained to seek informed consent respecting the current guidelines. The patient should be informed about risks and benefits of the research. Informed consent process training following SOP guidelines is a recommended training as part of our safety program. More health care quality improvement (QI) and health care quality improvement research (QIR) should be conducted to promote a learning health care system (Carroll et al., 2015).

Safety reporting:

In clinical trials, record of efficacy and safety profile of the investigational drug is maintained to evaluate the benefit: risk ratio of the drug. Adverse events are reported to the Principal Investigator by the research participants during the conduct of the trial. In such an incident, the principal investigator is ethically bound to report the event to the sponsors and responsible for the medical management of adverse events.

Organizations should follow the adverse event (A/E) and serious adverse event (SAE) guidelines of reporting as provided by the regulatory bodies and sponsors. Serious adverse event includes: death, inpatient hospitalization, disability, congenital anomaly or life threatening event. SAE should be reported within 24 hrs. of occurrence of the SAE. In case of such incidents adverse event narratives are written which includes complete description of the event, demography, medical history, lab test results, dose of study drug, concomitant medications. Adverse event reporting plays vital role in quality control.

Adverse event assessment and reporting helps in adjudication in cases where the A/E is related to the investigational product. In the clinical trial agreement, the institution agrees to provide medical treatment and financial compensation for any injury during the trial. Such reporting helps human participants to receive financial compensation, also helps in analysis of adverse events for better understanding of safety profile of the investigational drug.

The clinical data interchange standards consortium (CDISC) has developed data standards. These standards enable development of new software's to analyze adverse event narratives and safety reports. JMP clinical software utilizes CDISC standards to streamline the review of data. As per CDISC domain data is presented on y axis and time is represented on x axis. Different symbols and colors are used on data spectrum. In a single panel, a reviewer has access to all data (Zink & Mann., 2012). AE narrative analytical process generates summary of all adverse events for a selected subject. These reporting tools help in flexible analysis. JMP clinical software assures quality in safety reporting. Our review recommends this software as part of safety program.

It's important to educate the Principal investigators of the trials to be vigilant about unscheduled visits of research participants. Real-time automatic alert system can help to report the A/Es in real time. This system is highly beneficial in phase I and high-risk clinical trials. Integration of information technology-driven automatic alert systems into the clinical trials will improve safety reporting and will enhance patient safety (Baek et al., 2020).

Safety reporting is essential for ethical outcome in clinical trials. Communication and training is essential for thorough understanding of what has to be reported, why it has to be reported, to whom it has to be reported and how should it be reported (Tucker AL, Edmondson AC., 2003). Reporting hazards and problems help in organizational learning and help to improve patient safety.

Incident reporting plays a vital role in safety management. It leads to changes in staff's current knowledge, training and care processes. Attitude to incident reporting system should be positive. Incident reporting system helps in bringing awareness amongst the health care organizations.

Conclusion:-

Our proposed Safety Program has been designed on evidence-based practice and is dedicated to achieve patient safety and quality assurance in clinical trials. Our program will help institutions to develop guidelines for better research outcomes, improve quality of projects, help in data management, provide training opportunities to site staff, ensure professional excellence and will help stakeholders to collaborate for patient safety (Griffin et al., 2010; Brehaut et al., 2019).

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